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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/306,749 05/07/99 MEADE

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EXAMINER

HM22/0813

ZITOMER, S

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

08/13/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/306,749

Applicant(s)

MEADE et al.

Examiner

Stephanie Zitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 14, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-25 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

DETAILED ACTION

Prosecution status

1. Receipt of the response and Terminal Disclaimer filed May 14, 2001 is acknowledged.
2. The formal drawings submitted May 14, 2001 have been approved by the draftsman.
3. The double patenting obviousness type rejection set forth in the previous Office action, paper no. 8, mailed December 8, 2000, has been withdrawn in view of acceptability of the Terminal Disclaimer.
4. All other rejections set forth in paper no. 8 are maintained in this Final Office Action. Applicant's arguments are addressed in a single paragraph following the rejections as they are all based on the lack of disclosure of the claimed invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejection under 35 U.S.C. 101: Lack of specific asserted utility

5. Claims 12-25 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. The specification fails to teach the claimed "nucleoside comprising a covalently attached electron transfer moiety" and thus fails to disclose an asserted specific and substantial utility for the nucleoside. One of skill in the art would not have expected that a nucleoside with attached electron transfer moiety which comprises a transition metal as known in the art and taught in the specification would be readily incorporated during either an enzymatic synthesis or a chemical synthesis due to the bulky structure of such electron transfer groups which would interfere with the necessary contact between the reactants. For example, Bannwarth et al. (5,278,043) discloses nucleic acids in which electron transfer compounds are attached to the terminal nucleotides or are substituted for some of the internal nucleotides. Notably, the reference does not teach the incorporation of nucleosides with bulky electron transfer moieties attached thereto during nucleic acid synthesis. Therefore, the claimed nucleosides do not have an established utility. Furthermore, the specification teaches attachment of the electron transfer moiety to an amino-modified nucleotide after the modified nucleotide has been incorporated into the nucleic acid which teaches away from the claimed "nucleoside

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comprising a covalently attached electron transfer moiety". Note that because the claimed invention is not supported by a specific asserted utility for the reasons set forth above credibility cannot be assessed.

Rejection under 35 U.S.C. 112, first paragraph: Lack of enablement

6. Claims 12-25 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Rejection under 35 U.S.C. 112, first paragraph: Lack of written description

7. Claims 12-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although Figures 4A and 4B describe a nucleoside comprising a covalently attached electron transfer group, the specification fails to describe the "nucleoside [or nucleotide] comprising a covalently attached electron transfer moiety" as a molecule that is distinct from a nucleic acid molecule. In the method of making nucleic acids comprising electron transfer moieties described in the specification at page 20 and in Example 1 at pages 37-40, the nucleosides are modified by addition of an amino group at the 2' or 3' position and the electron transfer moiety is attached via the amino group after synthesis of the nucleic acid in which the amino-modified nucleosides are incorporated (page 20, lines 10-18). Thus, the specification further fails to teach how to make the claimed invention nucleoside or nucleotide. Furthermore, one of skill in the art would not have expected that a nucleotide with attached electron transfer moiety which comprises a transition metal as taught in the specification would be readily incorporated during either an enzymatic synthesis or a chemical synthesis due to the bulky structure of such electron transfer groups which would interfere with the necessary contact between nucleotides. For example, Bannwarth et al. (5,278,043) discloses nucleic acids in which electron transfer compounds are attached to the terminal nucleotides or are substituted for some of the internal nucleotides. Nucleosides with bulky electron transfer moieties attached are not incorporated during nucleic acid synthesis. The present specification simply does

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not describe a nucleoside with an electron transfer group attached thereto or a method of incorporating such nucleoside in a nucleic acid during synthesis. In addition to enablement the first paragraph of 112 requires a "written description". As set forth by the Court in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. It is clear from the lack of description in the specification that applicant did not contemplate the claimed nucleoside comprising a covalently attached electron transfer moiety at the time the claimed invention application was filed.

Response to applicant's arguments

8. Applicant's arguments filed May 14, 2001 have been fully considered but they are not persuasive. The arguments attempt to show by reference to the specification that the claimed invention nucleoside or nucleotide comprising an electron transfer moiety covalently attached to the ribose is disclosed and described therein. However, as pointed out in the rejections, the nucleosides and nucleotides in the specification are modified only with a small chemical group such as an amino moiety and the electron transfer moiety is reacted with that group to form a covalent bond after the modified nucleosides or nucleotides have been incorporated into the nucleic acid during synthesis. Therefore, the *per se* nucleoside or nucleotide with covalently attached electron transfer moiety is not disclosed as a discrete molecule as claimed.

Conclusion

9. **No claim is allowed.**

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action.

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In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stephanie Zitomer, Ph.D.

August 8, 2001

STEPHANIE ZITOMER
PRIMARY EXAMINER